



## **Guidelines for Security Printer Policies and Procedures** (Health & Safety Code section 11161.5 et seq.)

Under California law security printer applicants must have policies and procedures that address four general areas. A copy of your policies and procedures must be submitted with your application to produce controlled substance prescription forms.

The following methods and criteria are provided for your review when writing policies and procedures that meet or exceed the requirements of California law:

### **1) Prescriber Identification and Verification of Prescribing Privileges**

*Policies and procedures for verifying the identity of the prescriber ordering controlled substance prescription forms. Before printing any controlled substance prescription forms a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges, which permits the prescribing of controlled substances. (Health & Safety Code section 11161.5, subdivisions (b)(2), & (f))*

#### **♦ License Verification**

License verification of the prescriber can be accomplished online, free of charge, by visiting [www.dca.ca.gov](http://www.dca.ca.gov). Click on the "License and Complaint History" icon, then choose the prescriber's license type (i.e., physician under Medical Board, dentist under Dental Board etc.). Another option is to order a monthly list of current licensees for each of the prescriber boards, in either hard copy or as a data file, through the Department of Consumer Affairs, Public Sales Office by calling (916) 323-7018. There is a fee for this service.

Verification of the prescriber's State license must occur with each prescriber's order, every time he or she orders forms. If the "License Status" indicates anything other than Clear, Renewed/Current, or Active the security printer must call the applicable licensing board below for verification the licensee is permitted to practice and write controlled substance prescriptions.

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|-------------------------------|--------------------------------|
| ♦ Medical Board of California | 916-263-2499 or 1-800-633-2322 |
| ♦ Dental Board of California  | 916-263-2300                   |
| ♦ Veterinary Medical Board    | 916-263-2610                   |
| ♦ Osteopathic Medical Board   | 916-263-3100                   |
| ♦ Board of Podiatric Medicine | 916-263-2647                   |
| ♦ Board of Registered Nursing | 916-322-3350                   |

#### **♦ Authority to Prescribe Controlled Substances**

The security printer will also need to check the prescriber's authority to write controlled substance prescriptions. Prescribers must register with the Drug Enforcement Administration (DEA) and obtain a DEA Registration number before they can write controlled substance prescriptions. The security printer must obtain a copy of the prescriber's current DEA registration with every order (even repeat business) and verify that the registration is not expired or otherwise impaired. All orders for prescription forms must be directed to the address on the DEA registration, no exceptions. Refer the prescriber to the DEA to update his or her registration if there is a discrepancy.



♦ ***Restricted Prescribers***

Security printer's should also check the Board of Pharmacy's website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) to verify that a prescriber's authority to write controlled substance prescriptions has not been recently restricted due to civil, criminal, administrative action, or order of the court issued pursuant to Health & Safety Code section 11161. The Board of Pharmacy will maintain a list on its website under the link for Security Printer Approval to Produce Controlled Substance Prescription Forms titled "Restricted Prescribers". The list will be updated regularly as new information becomes available.

2) **Verification of Delivery to Prescriber and Proof of Such Delivery to the Printer**

*Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers. Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by means that requires a signature signifying receipt of the package and provisions of that signature to the security printer. (Health & Safety Code section 11161.5, subdivisions (b)(3), & (g))*

Delivery of controlled substance prescription forms must be in person or via certified mail or other means where a signature is required upon delivery and a return receipt showing proof of that delivery automatically sent back to the security printer. This proof of delivery record must be kept for three years. Note: Online proof of delivery verification is acceptable but please verify with the carrier that the records are available online for a full three years. Please see item #3 below.

3) **Records Retention**

*Policies and procedures for the retention of ordering and delivery records in a readily retrievable manner for individual prescribers for three years. (Health & Safety Code section 11161.5, subdivision (h))*

Procedures should describe the documents that will be retained for three years (e.g., order forms, production order tracking documents including batch/lot numbers, copies of DEA registration and state license, proof of delivery from carrier, shipping documents, etc.) and in what format the documents will be retained (hard copy or electronic). Hard copy and electronic documents should be stored in such a way to prevent loss from unforeseen disaster such as fire or flood. They should also be stored in locked facilities or cabinets. Electronic documents should be backed up onto disk or CD.

The records must be in a readily retrievable format. For example, law enforcement may inquire about the sale of prescription forms to a particular doctor over the past year. Where does law enforcement go to obtain the records? How quickly can this information be provided to law enforcement, and what information will be provided?

4) **Security for Production and Distribution of Controlled Substance Prescription Forms**

*Adequate security procedures relating to the production and distribution of controlled substance prescription forms. (Health & Safety Code section 11161.5, subdivision (d)(5))*

Security printers are responsible for establishing and maintaining effective controls and security procedures to prevent loss or theft of raw materials used to make controlled substance prescription forms as well as partially finished and finished forms. The following elements may apply to your security policies and procedures relating to the production and



distribution of controlled substance prescription forms. However, some elements may not apply to your specific business structure:

- a) The security printer has the facilities and specialized equipment necessary to produce controlled substance prescription forms that contain all of the security features outlined in Health & Safety Code section 11162.5 et seq.
- b) If using distributors to market your product, policies and procedures should address the ordering process and distributor's responsibilities. The approved security printer is always responsible for retaining all related ordering, production, and delivery records for 3 years, therefore, policies and procedures should specify the documents you will require from your distributors, as well as the format desired, the expected timeframe and the desired method for receiving the documents.
- c) Secure production and storage facilities (i.e., alarm systems, vaults, locked cabinets and storage facilities, security guards, security cameras, card key ID access, etc.)
- d) Accountability and tracking procedures at all phases of product development, storage, and distribution. (Limited access to keys, raw materials, and stored finished and partially finished product, electronic tracking systems, secure transport between security printer facilities, use of the buddy system (dual custody) in controlled access areas, raw materials and finished product as well as ink supplies and form templates are housed in locked facilities and keys are secured, restricted access to all visitors, etc.)
- e) Procedures for the destruction of discarded or waste materials during production. Procedures for the pickup and destruction of returned product from customers.
- f) Use of discrete shipping cartons to minimize potential theft.
- g) Database, network, and internet systems have updated firewalls and virus protection in place to prevent electronic breach of information captured during the telephonic and online product ordering, tracking, storage, distribution, destruction etc.
- h) Policy for internal investigation if an employee is suspected of or found to be tampering with or stealing raw materials, or finished or partially finished product. Include steps to prevent future incidents.
- i) Operational recovery and business continuity plans in place in case of unforeseen disaster or disruptions. Are data files backed up regularly? Are hard copy documents safeguarded from fire/flood?
- j) A statement that the security printer will (1) submit annually the location, name, and title of the security printer's agent for service of process in California; and (2) submit within 30 days after any change of offices, principal corporate officers, or managing general partners.